



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,863	08/20/2003	Jonathan C. Heller	29191-707	7685
21971	7590	10/13/2005	EXAMINER	
WILSON SONSINI GOODRICH & ROSATI			DEJONG, ERIC S	
650 PAGE MILL ROAD			ART UNIT	
PALO ALTO, CA 94304-1050			PAPER NUMBER	

1631

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/645,863

Applicant(s)

HELLER ET AL.

Examiner

Eric S. DeJong

Art Unit

1631

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 12 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see continuation sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1,3,7-10,14,15,17-20,22-27,29-31,38,41 and 42.  
Claim(s) withdrawn from consideration: 4-6,11-13,21,32-37,39,40 and 43.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.  
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 17 June 2005  
13. ☐ Other: \_\_\_\_\_.

500

Continuation of item #3. NOTE:

Since the set of claims filed by applicant on 09/12/2005 are not in compliance with 37 C.F.R. § 1.121, the proposed amendments to the claims contained therein have not been considered by the Examiner. Further, arguments filed by applicants on 09/12/2005 have been considered only with respect to the previous version of the claims filed by applicants on 05/16/2005.

Continuation of item #11. NOTE:

The rejections in the previous Office action mailed 06/15/2005 are maintained for reasons of record.

Claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Olek et al. in view of Fouillet et al. as evidenced by Chambers et al.

Applicants argue that cited references, individually or in combination, fail to teach or suggest the claimed limitation of "marketing diagnostic products that use said representative patterns wherein said diagnostic products are marketed with a disposable microfluidics device". Applicants further assert that the claim term "specific identity" is used throughout the specification and in the claims in its ordinary meaning and that a specific identity of a protein would include, for example, amino acid sequence or its function.

Applicants arguments have been fully considered but are not found persuasive. Applicants statement that the claim term "specific identity" includes, for example, the function of a protein is found inconsistent with the instantly claimed invention. In performing the method steps a) through c) of claim 1 will result in identifying proteins from clinical and control samples, thereby identifying proteins that provide for a reproducible representative pattern for a generic clinical phenotypic state. As such, the proteins present in a representative pattern have a been identified to the extent that they are involved, either directly or indirectly, with a particular clinical phenotypic state and, therefore, their function is at least partially established. Thus, the argument that that the claim term "specific identity" of a protein may include the function of said protein is inconsistent the instantly claimed method.

Applicants remaining arguments and characterization of the cited references are not directed to the specific merits presented in the previous Office action and are, therefore, not found persuasive.

EDJ

EDJ

*John S. Brusca 5 October 2005*  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER

**Notice of Non-Compliant  
Amendment (37 CFR 1.121)**

Application No.

10/645,863

Examiner

Eric S. DeJong

Applicant(s)

HELLER ET AL.

Art Unit

1631

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

The amendment document filed on 12 September 2005 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other \_\_\_\_\_.
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other \_\_\_\_\_.
- ☒ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☒ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☐ E. Other: \_\_\_\_\_.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

**TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:**

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

**Extensions of time** are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

**Failure to timely respond** to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

**Non-entry** of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.